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10/567,077	02/03/2006	Frank Theobald	5121002053	2323

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William F Lawrence  
Frommer Lawrence & Haug  
745 Fifth Avenue  
New York, NY 10151

EXAMINER
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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Howard C. Lee  
FROMMER LAWRENCE & HAUG LLP  
745 FIFTH AVENUE  
NEW YORK, NY 10151

In re Application of :  
THEOBALD et al. :  
Serial No.: 10/567,077 : Decision on Petition  
Filed: February 3, 2006 :  
Attorney Docket No.: 512100-2053 :

This letter is in response to the letter filed on September 29, 2008 requesting reconsideration of the finality of the restriction requirement. It is presumed that the Petition from requirement for restriction was made under 37 C.F.R. 1.144 and has been treated as such.

## BACKGROUND

This application was filed as a national stage application under 35 USC 371 of PCT/EP04/08221 and as such, is eligible for unity of invention practice.

On February 20, 2008, the examiner mailed to the applicant a restriction requirement requiring two separate election of species requirements. The first requirement requested applicant to elect between the supporting layer of a covering file which is or which is not comprised of organic polymer. The second requirement requested applicant to elect between an ormocer layer that is applied to one or to both surfaces of the supporting layer.

On April 3, 2008, applicant elected the situation where the supporting layer is composed of at least one organic polymer layer for the first election requirement and the situation where the at least one ormocer layer is applied on both sides of the supporting layer (see claim 8) with traverse. The response argued that the PCT was not subjected to an election of species requirement and there has been no showing that the combination of elements does not represent a single general concept.

On May 28, 2008, the examiner mailed to applicant a non-final Office action in which the examiner stated that the applicant did not point out the supposed errors in the restriction requirement. The election of treated as an election without traverse and the examiner made the lack of unity requirement Final. Claim 7 was withdrawn from consideration as being directed to

the non-elected species. Generic claims 1-6, 9 and 10 were examined along with claim 8, directed to the elected species. The claims were rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph and 35 U.S.C. 103.

On September 29, 2008, applicants filed this petition to request that the Office reconsider the finality of the restriction requirement, responded to the outstanding rejections and filed amendments to the claims.

## DISCUSSION

The petition and file history have been carefully considered.

The two election of species requirements have been separately reconsidered.

The first requirement requested applicant to elect between the supporting layer of a covering film which is or which is not comprised of organic polymer. Upon review, independent Claim 1 requires a covering film composed of at least one supporting layer which is composed of at least one organic polymer. The independent claim and all dependent claims appear to require at least one organic polymer. Thus, the first requirement to elect a species supporting layer of a covering film which is or which is not comprised of organic polymer is improper and withdrawn. The remainder of this decision will focus on the second election of species requirement.

The second requirement requested applicant to elect between an ormocer layer that is applied to one or to both surfaces of the supporting layer. Applicant elected that the at least one ormocer layer is applied on both sides of the supporting layer. This election reads upon the species of claim 8 below, and is encompassed by generic claims 1-6, 9 and 10.

8. (Currently amended) The dermal or transdermal therapeutic system as claimed in claim 1, characterized in that ~~in each case~~ at least one ormocer layer is applied on both surfaces of the supporting layer.

The petition correctly states that the Office Action of May 28, 2008 made the lack of unity requirement final without providing a rationale for maintaining the election of species. The reasons are supplied as follows:

Relevant sections of PCT International Search and Preliminary Examination Guidelines (published January 2004) state

Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. (paragraph 10.02)

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. (paragraph 10.07)

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. (paragraph 10.08)

In this instance, the species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the species lack unity of invention because even though the species of these groups require the technical feature of a therapeutic device for the transdermal administration of a medicament, comprising a reservoir containing an active agent, a release layer formed on the inner surface of the reservoir (a peelable protective layer) and an active agent impermeable backing layer formed on the outer surface, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Kwiatek et al. See the 35 U.S.C. 103(a) rejection of record.

MPEP 809 provides guidance on the examination practice of species encompassed by a generic claim:

The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims; and
- (B) subcombination claims linking plural combinations.

Where an application includes claims to distinct inventions as well as linking claims, restriction can nevertheless be required.

The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.

Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions.

In this application, the claims are rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph and 35 U.S.C. 103 for the elected species, namely, the ormocer layer is applied on both sides of the supporting layer. Because the pending claim set does not include an allowable generic linking claim and because not all claims to the election species are in condition for allowance, there is no obligation on the examiner at this time to withdraw the election of species requirement or to examine non-elected species.

The argument that designated Offices should not raise an objection to lack of unity if no such opinion in is expressed in the international search report has been considered but found not persuasive for the following reasons. The opinions on novelty and inventive step expressed at the international stage are "non-binding" on any national Office (see 37 CFR 1.484, for example). The International authority's opinion on unity is similarly not considered to be binding opinions since neither the PCT nor the regulations under the PCT indicate that they are "binding". 37 CFR 1.499 states "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted." Thus there's no stipulation that a lack of unity is prohibited in the event that the international search authority did not make a lack of unity determination.

For these reasons, the requirement to elect a species of an ormocer layer applied to one or two surfaces is maintained, in light of the non-allowability of the generic Claim 1. Claim 7 remains withdrawn from consideration.

## DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above.

The first election of species requirement (if the supporting layer of a covering file is or is not comprised of at least one organic polymer ) has been withdrawn.

The second election of species requirement is maintained. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim

**The application will be forwarded to the examiner for further action consistent with this decision and for consideration of the papers filed September 29, 2008.**

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions about this decision, please contact Special Program Examiner Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George Elliott  
Director, Technology Center 1600  
jb/jg